

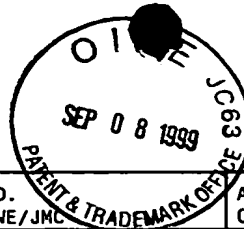
FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1483.0130002/RWE/JMC	APPLICATION NO. 09/321,882
	APPLICANT UPASANI <i>et al.</i>	
	FILING DATE May 28, 1999	GROUP 1614

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
BB	AA1	3,135,744 ✓	06/02/1964	Ercoli <i>et al.</i>	260	239.55	04/03/1962
	AB1	3,316,146 ✓	04/25/1967	Wechter	167	52	03/30/1964
	AC1	3,822,298 ✓	07/02/1974	Clayton <i>et al.</i>	260	397.4	11/10/1972
	AD1	3,882,151 ✓	05/06/1975	Phillipps <i>et al.</i>	260	397.45	12/16/1971
	AE1	3,943,124 ✓	03/09/1976	Phillipps <i>et al.</i>	260	239.55R	06/20/1974
	AF1	3,953,429 ✓	04/27/1976	Cook <i>et al.</i>	260	239.55	02/19/1974
	AG1	3,959,260 ✓	05/25/1976	Phillipps <i>et al.</i>	260	239.5	07/16/1974
	AH1	3,969,345 ✓	07/13/1976	Phillipps <i>et al.</i>	260	239.55	02/20/1975
	AI1	3,998,829 ✓	12/21/1976	Phillipps <i>et al.</i>	260	239.5	05/08/1973
	AJ1	4,192,871 ✓	03/11/1980	Phillipps <i>et al.</i>	424	241	05/22/1978
BB	AK1	4,197,296 ✓	04/08/1980	Phillipps <i>et al.</i>	424	241	09/26/1978

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
BB	AL1	DE 1 050 765 ✓	08/05/1959	Germany			Yes No
	AM1	GB 839,911 ✓	06/29/1960	United Kingdom			Yes No
	AN1	FR 1849M ✓	06/10/1963	France			Yes No
	AO1	FR 1,437,361 ✓	03/28/1966	France			Yes No
BB	AP1	DE 2 156 094 ✓	05/18/1972	Germany			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
BB	AR	1 ✓	Atkinson, R.M. <i>et al.</i> , "Action of Some Steroids on the Central Nervous System of the Mouse. 11. Pharmacology," <i>J. Med. Chem.</i> 8:426-432 (1965).
	AS	1 ✓	Atwal, K.S. <i>et al.</i> , "On Cardioactive Steroids. VI. The Synthesis of 17 α -Methyl Cardenolides," <i>Heterocycles</i> 19: 641-646 (1982).
	AT	1 ✓	Bauer, P.E. <i>et al.</i> , "A Synthesis of 3 β -Hydroxy-5 β , 14 α -bufa-20, 22-dienolide from Deoxycorticosterone," <i>J. Org. Chem.</i> 48:34-39 (1983).

EXAMINER Bada	DATE CONSIDERED 11/19/89
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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

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1483.0130002/RWE/JMCAPPLICATION NO.
09/321,882APPLICANT
UPASANI *et al.*FILING DATE
May 28, 1999GROUP
1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
BB	AA2	4,297,350 ✓	10/27/1981	Babcock <i>et al.</i>	424	238	10/10/1978
	AB2	5,120,723 ✓	06/09/1992	Gee <i>et al.</i>	514	176	05/10/1990
	AC2	5,208,227 ✓	05/04/1993	Gee <i>et al.</i>	514	172	02/13/1991
	AD2	5,232,917 ✓	08/03/1993	Bolger <i>et al.</i>	514	176	08/13/1991
	AE2	5,319,115 ✓	06/07/1994	Tahir <i>et al.</i>	552	609	03/04/1992
	AF2	5,591,733 ✓	01/07/1997	Bolger <i>et al.</i>	514	172	08/02/1992
BB	AG2	5,939,545 ✓	08/17/1999	Upasani <i>et al.</i>	540	110	07/02/1997
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
BB	AL2	GB 1 380 248 ✓	01/08/1975	United Kingdom			Yes No
	AM2	GB 1 432 135 ✓	04/17/1976	United Kingdom			Yes No
	AN2	GB 1 581 235 ✓	12/10/1980	United Kingdom			Yes No
	AO2	WO 93/03732 ✓	03/04/1993	WIPO			Yes No
BB	AP2	WO 94/27608 ✓	12/08/1994	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

BB	AR	2 ✓	Buckett, W.R. <i>et al.</i> , "Pancuronium Bromide and Other Steroidal Neuromuscular Blocking Agents Containing Acetylcholine Fragments," <i>J. Med. Chem.</i> 16:1116-1124 (1973).
	AS	2 ✓	Bull, J.R. and Hoadley, C., "Cycloaddition-Oxidative Cleavage Pathways to 14 β -Formyl-19-norsteroids," <i>Tetrahedron Lett.</i> 35:6171-6174 (August 1994).
BB	AT	2 ✓	Chanoine, F. <i>et al.</i> , "Isolation and Identification of Major Metabolites of Tixocortol Pivalate in Human Urine," <i>Drug Metab. Disp.</i> 15:868-876 (1987).

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BB	AM3	WO 96/16076 ✓	05/30/1996	WIPO			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
BB	AR ✓	3	Cocker, J.D. et al., "Action of some steroids on the central nervous system of the mouse. I. Synthetic methods," <i>Chem. Abstr.</i> 63: 4361f (1965).
	AS ✓	3	Cocker, J.D. et al., "Action of Some Steroids on the Central Nervous System of the Mouse. I. Synthetic Methods," <i>J. Med. Chem.</i> 8:417-425 (1965).
BB	AT ✓	3	Cross, A.D. et al., "Steroids CCLXXII. Biologically-Active Labile Ethers III. A New Class of Potent Estrogens," <i>Steroids</i> 5:557-583 (1965).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

BB 37	✓ AR	4	Drasar, P. <i>et al.</i> , "Alternative Synthesis of Steroidal Maleimides," <i>Collection Czechoslovak Chem. Comm.</i> 48: 1224-1232 (1983).
	✓ AS	4	Engel, Ch.R. <i>et al.</i> , "Favorsky Rearrangements of α -Halogenated Acetylcycloalkanes," <i>J. Org. Chem.</i> 47:4485-4491 (1982).
	✓ AT	4	Ercoli, A. and Gardi, R., "17 β -Alkenyloxyandrostanes," <i>Chem. Abstr.</i> 66:38147d (1967).

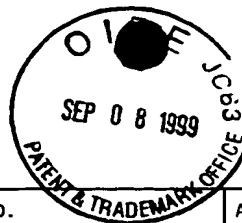
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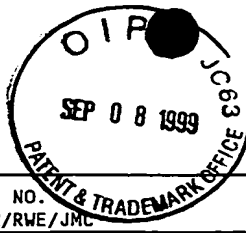
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

BP	✓ AR	5	Falconi, G., "Steroid-17 β -yl acetals and enol ethers: New orally active, C-17 α not alkylated, anabolic compounds," <i>Chem. Abstr.</i> 64:17971f (1966).
	✓ AS	5	Farmaceutici Italia Soc. Anon., "21-Triphenylmethyl ethers of corticosteroids," <i>Chem. Abstr.</i> 56:530h (1962).
BP	✓ AT	5	Gee, K.W. and Yamamura, H.I., "Benzodiazepines and Barbiturates: Drugs for the Treatment of Anxiety, Insomnia, and Seizure Disorders," in: <i>Drugs in Central Nervous System Disorders</i> , D.C. Horwell (Ed.), New York: Marcel Dekker, pp. 123-147 (1985).

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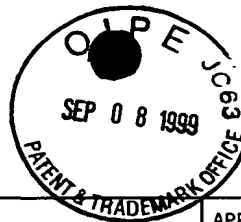
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
BB	✓ AR	6	Gee, K.W. <i>et al.</i> , "GABA-dependent modulation of the Cl ⁻ ionophore by steroids in rat brain," <i>Eur. J. Pharmacol.</i> 136:419-423 (1987).
	✓ AS	6	Gee, K.W. <i>et al.</i> , "Steroid Modulation of the Chloride Ionophore in Rat Brain: Structure-Activity Requirements, Regional Dependence and Mechanism of Action," <i>J. Pharmacol. Exp. Ther.</i> 246:803-821 (1988).
BB	✓ AT	6	Grieco, P.A. and Stuk, T.L., "Remote Oxidation of Unactivated C-H Bonds in Steroids via Oxometalloporphinates," <i>J. Am. Chem. Soc.</i> 112:7799-7801 (1990).

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

3B	AR	Z	Harrison, N.L. <i>et al.</i> , "Structure-Activity Relationships for Steroid Interaction with the γ -Aminobutyric Acid _A Receptor Complex," <i>J. Pharmacol. Exp. Ther.</i> 241:346-353 (1987).
	AS	Z	Hawkinson, J.E. <i>et al.</i> , "Correlation of Neuroactive Steroid Modulation of [³⁵ S]t-Butylbicyclopentylphosphorothionate and [³ H]Flunitrazepam Binding and γ -Aminobutyric Acid _A Receptor Function," <i>Molec. Pharmacol.</i> 46:977-985 (November 1994).
	AT	Z	Hu, Y. <i>et al.</i> , "Neurosteroid Analogues: Structure-Activity Studies of Benz[e]indene Modulators of GABA _A Receptor Function. 1. The Effect of 6-Methyl Substitution on the Electrophysiological Activity of 7-Substituted Benz[e]indene-3-carbonitriles," <i>J. Med. Chem.</i> 36:3956-3967 (1993).

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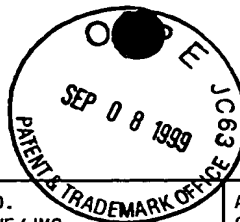
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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
BB	AR	8 ✓	Ihara, M. <i>et al.</i> , "Stereoselective Total Synthesis of Testosterone and Androsterone via A/B-Ring Construction of the Steroidal Ring System by Intramolecular Diels-Alder Reaction," <i>J. Chem. Soc. Perkin Trans. I</i> :117-123 (1986).
	AS	8 ✓	Im, W.B. <i>et al.</i> , "Studies on the Mechanism of Interactions between Anesthetic Steroids and γ -Aminobutyric Acid-A Receptors," <i>Mol. Pharmacol.</i> 37:429-434 (1990).
BB	AT	8 ✓	Kirk, D.N. and Yeoh, B.L., "New Syntheses of 19,21-Dihydroxypregn-4-ene-3, 20-dione, 21-Hydroxy-19-norpregn-4-ene-3, 20-dione, and 11 β ,19,21-Trihydroxypregn-4-ene-3,20-dione," <i>J. Chem. Soc. Perkin Trans. I</i> :2945-2951 (1983).

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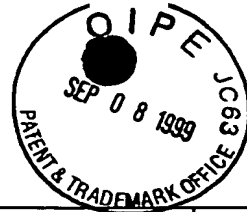
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
BP	✓ AR	2	Laboratoires Français de Chimiothérapie, "Derivatives of etiocholane," <i>Chem. Abstr.</i> 55:619d (1961).
	✓ AS	2	Lambert <i>et al.</i> , "Actions of synthetic and endogenous steroids on the GABA _A receptor," <i>Trends Pharmacol. Sci.</i> 8:224-227 (1987).
BP	✓ AT	2	Lan, N.C. <i>et al.</i> , "Identification and Characterization of a Pregnane Steroid Recognition Site That is Functionally Coupled to an Expressed GABA _A Receptor," <i>Neurochem. Res.</i> 16:347-356 (1991).

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

FB	✓ AR	10	Lalièvre, V. <i>et al.</i> , "Correlation Between Binding Activity, Inhibition of Lymphoblastic Transformation and Metabolism of Tixocortol 21 Pivalate in Mouse Thymocytes," <i>Agents and Actions</i> 21:262-265 (1987).
	✓ AS	10	Lawrence, D.K. and Gill, E.W., "Structurally specific effects of some steroid anesthetics on spin labeled liposomes," <i>Chem. Abstr.</i> 84:54385g (1976).
	✓ AT	10	Lewbart, M.L. and Mattox, V.R., "Oxidation of steroidal α -ketols to glyoxals with cupric acetate," <i>Chem. Abstr.</i> 59:6474c (1963).

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	AO						Yes No
	AP						Yes No

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BB	✓ AR	11	Lewbart, M.L. and Mattox, V.R., "Oxidation of Steroidal α -Ketols to Glyoxals with Cupric Acetate," <i>J. Org. Chem.</i> 28:2001-2006 (1963).
	✓ AS	11	Lloyd, K.G. and Morselli, P.L., "Psychopharmacology of GABAergic Drugs," in: <i>Psychopharmacology: The Third Generation of Progress</i> , H.Y. Meltzer (Ed.), New York: Raven Press, pp. 183-195 (1987).
	✓ AT	11	Majewska, M.D. <i>et al.</i> , "Steroid Hormone Metabolites are Barbiturate-Like Modulators of the GABA Receptor," <i>Science</i> 232:1004-1007 (1986).

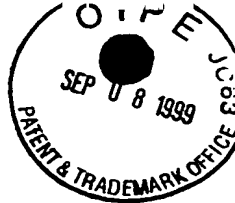
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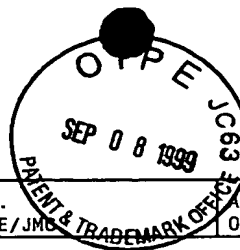
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	AP						Yes No

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BB	✓ AR	12	Neef, G. <i>et al.</i> , "Reaction of Unsaturated Sulfoxides with Alkylolithiums," <i>Tetrahedron Lett.</i> 21:903-906 (1980).
/	✓ AS	12	Phillipps, G.H., "Structure-Activity Relationships in Steroidal Anaesthetics," <i>J. Steroid Biochem.</i> 6:607-613 (1975).
/	✓ AT	12	Phillipps, G.H., "Structure-Activity Relationships in Steroidal Anaesthetics," in: <i>Molecular Mechanisms in General Anesthesia</i> , Halsey, M.J. <i>et al.</i> (Eds.), Glaxo Symposium, pp.32-47 (1974).

EXAMINER Bado	DATE CONSIDERED 11/19/99
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.6 Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
1483.0130002/RWE/JMCAPPLICATION NO.
09/321,882APPLICANT
UPASANI *et al.*FILING DATE
May 28, 1999GROUP
1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

PB	✓ AR	13	Purdy <i>et al.</i> , "Synthesis, Metabolism and Pharmacological Activity of 3 α -Hydroxy Steroids Which Potentiate GABA-Receptor-Mediated Chloride Ion Uptake in Rat Cerebral Cortical Synaptoneurosomes," <i>J. Med. Chem.</i> 33:1572-1581 (1990).
	✓ AS	13	Re, L., "Reductive removal of the 17 α -hydroxyl group of the cortical side-chain," <i>Chem. Abstr.</i> 60:1820d (1964).
	✓ AT	13	Re, L., "Reductive Removal of the 17 α -hydroxyl Group of the Cortical Side-Chain," <i>Steroids</i> 2:465-470 (1963).

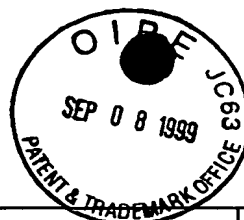
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	FILING DATE May 28, 1999	GROUP 1614

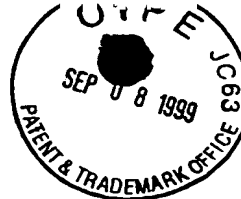
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
7B	✓ AR	14	Roussel-UCLAF, "Esters of 3 α -hydroxyetiocholan-11-one," <i>Chem. Abstr.</i> 67:1916g (1969).
	✓ AS	14	Rubin, M., "19-Methyl-19-acyloxystrophanthidins," <i>Chem. Abstr.</i> 59:11617b (1963).
7B	✓ AT	14	Templeton, J.F. <i>et al.</i> , "Stereoselective Reduction of C-2 Substituted Steroid C-3 Ketones with Lithium Tris-(R,S-1,2-Dimethylpropyl)-Borohydride and Sodium Borohydride," <i>Steroids</i> 48:339-346 (1986).

EXAMINER <u>7ada</u>	DATE CONSIDERED <u>11/19/99</u>
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	AN						Yes No
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
BB	✓ AR	15	Warnant, J. and Joly, R., "Testan-3 α -ol-11-one and its esters," <i>Chem. Abstr.</i> 55:3660b (1961).
	✓ AS	15	Wieland, S. <i>et al.</i> , "Comparative Behavioral Characterization of the Neuroactive Steroids 3 α -OH, 5 α -pregan-20-one and 3 α -OH, 5 β -pregnan-20-one in Rodents," <i>Psychopharmacol.</i> 118:65-71 (March 1995).
BB	✓ AT	15	English abstract of French Patent Document No. FR 1849M (Reference AN1), Derwent abstract no. 66-08474F/00 (1963).

EXAMINER Fado	DATE CONSIDERED 11/19/99
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

BB	AR	16	English abstract of French Patent Document No. FR 1, 437, 361 (Reference A01), Derwent abstract no. 66-05905F/00(1966).
	✓ AS	16	International Search Report issued by PCT International Searching Authority for Application No. PCT/US96/10115, mailed February 17, 1997.
	✓ AT	16	Communication Relating to the Results of the Partial International Search issued by ISA/EPO for PCT/US96/10115, filed June 6, 1996.

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